REMARKS/ARGUMENTS

The rejections presented in the Office Action dated July 24, 2006 (hereinafter Office Action) have been considered. Claims 1-17, 19-40, and 43-44 remain pending in the application. Claims 18, 41, and 42 have been cancelled. Of the pending claims, 3, 4, 9, 10, 14-16, 20, 22, 23, 28, 29, 33-35, 37, and 44 are withdrawn. Claims 1, 2, 5, 11-13, 17, 21, 24-27, 30-32, and 36 have been amended. The Applicant respectfully requests reconsideration and allowance of all pending claims.

Applicant notes the finality of the restriction/species election requirement. Applicant respectfully asserts that claims 1 and 21, as amended, are allowable linking claims. As set forth in MPEP 809, upon allowance of a genus linking claim, the restriction requirement between the linked inventions must be withdrawn. Any previously withdrawn claims which depend from or include all of the limitations of the allowable genus claim must be rejoined and examined for patentability.

The Examiner acknowledges the Applicant's claim for priority but states that the disclosure of the prior-filed Application No. 09/420,679 fails to provide adequate support or enablement in the manner required by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Applicant brings to the Examiner's attention that the specification of the present application repeats the disclosure of application 08/833281. As such, the specification of the present application omits subject matter from the specification of 09/420679 but does not add subject matter to the specification of 09/420679. Applicant respectfully asserts that the specification of the present application fully enables and supports the claims. Therefore, the present application is correctly identified as a division of application 09/420679 and is not a continuation-in-part application.

The Examiner states that adequate support or enablement is not provided by the prior-filed application because the prior-filed application "does not mention 'biventricular pacing therapy'" and/or "delivering biventricular pacing therapy in combination with the other elements as steps, such as providing a PVARP, multiple AV delays, modifying a

pacing timing sequence and then pacing at least one ventricle following a sensed AV delay."

With regard to the use of the term "bi-ventricular pacing therapy," Applicant has amended the claims so that the claims now recite pacing the ventricles rather than bi-ventricular pacing therapy. Applicant respectfully asserts that adequate support and enablement is provided by the prior-filed application because the prior-filed application describes pacing the ventricles in conjunction with providing a PVARP, detecting a disruption, modifying a pacing timing sequence and pacing the ventricles and avoiding PMT during pacing using the modified pacing timing sequence.

The present application describes on page 5 that "the principle object of the present invention is to provide a multi chamber pacemaker for pacing the selected ventricles of a patient suffering from heart failure." The application goes on to state that "a further object of the present invention is to provide a multi chamber pacemaker for pacing the selected ventricles of a patient wherein the selected ventricles are paced a preset time after an R wave is tracked by the pacemaker." The application further states that "another object of the present invention is to provide a method of multi chamber pacing which paces the ventricles a preset time after a P-wave is sensed during a PVARP interval following a sensed R-wave." On page 4, line 2, the application states "The purpose of the present invention is to provide a device and method of pacing continuously, without hysteresis, the ventricles of a patient's failing heart. . . ." Applicant believes it is very clear from these statements that the embodiments of the invention encompass methods and systems for pacing the ventricles to treat patients suffering from heart failure.

Various events can disrupt ventricular pacing. The disclosure describes alternate pacing timing sequences that promote continuous ventricular pacing, including a rate priority timing sequence (see, e.g., page 12, line 19), delay priority timing sequence (see, e.g., page 12, line 22), and modifications of the atrial tracking timing intervals after a sensed R-wave (see, e.g., page 20, line 5). Timing diagrams exemplifying these pacing sequences are provided in Figs. 6-22. Each of these timing diagrams indicates ventricular pacing Vp. Applicant asserts that, in light of the explicit statements in the specification that an object of

the invention is to provide pacing to the ventricles, in each case where a ventricular pace Vp is indicated in Figures 6-22, the Vp may be interpreted as a pace to both ventricles. As such, the specification describes in great detail pacing the ventricles in combination with other elements as steps, such as providing a PVARP, detecting disruptions of ventricular pacing, modifying the pacing timing sequence, and delivering pacing using the modified pacing timing sequence while avoiding PMT.

Claims 1, 2, 5-8, 11-13, 17-19, 21, 24-27, 30-32, 36 and 38-43 stand rejected under 35 U.S.C. §112, second paragraph, as failing to comply with the enablement requirement.

According to the Examiner, the specification does not describe a method and apparatus of delivering 'biventricular pacing therapy' and/or a method of apparatus of delivering biventricular pacing therapy in combination with the other elements and steps such as providing a PVARP, detecting a disruption of the pacing timing sequence, modifying a pacing timing sequence and then delivering pacing using the modified pacing timing sequence and avoiding PMT during delivery of the ventricular pacing. The Examiner contends that the specification does not mention "biventricular pacing therapy" or "delivering the bi-ventricular pacing therapy using a pacing timing sequence," "detecting a disruption of ventricular pacing," "modifying the timing sequence," "delivering the biventricular pacing therapy using the modified pacing timing sequence to promote ventricular pacing," and "delivering biventricular pacing therapy using the modified sequence and avoiding PMT." The Examiner states that the specification only provides specific details of the system and method of pacing a selected ventricle.

Without acquiescing to the reasons for the Examiner's rejections, the claims have been amended to remove the phrases "biventricular pacing therapy" and "pacing at least one ventricle." Applicant reasserts the arguments made above regarding the clear statements in the specification directed to pacing to the ventricles. Applicant asserts that, in light of the statements in the specification that an object of the invention is to provide pacing to the ventricles, in each case where a ventricular pace Vp is indicated in Figures 6-22, the Vp may be interpreted as a pace to both ventricles. As such, the specification describes in great detail pacing the ventricles in combination with other elements as steps, such as providing a

PVARP, such as providing a PVARP, detecting a disruption of the pacing timing sequence, modifying a pacing timing sequence and then delivering pacing using the modified pacing timing sequence and avoiding PMT during delivery of the ventricular pacing. The implementation of various features (PVARP, detecting a disruption, avoiding PMT, etc.) may operate exactly the same for pacing both ventricles as they do for pacing one ventricle.

Furthermore, one skilled in the art would readily understand that the instant application relates to heart failure therapy and that pacing both ventricles may be extrapolated from any examples where the ventricular pacing is indicated. To support the 112 rejection, the Examiner must "evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims." (MPEP 2104.06) Applicant respectfully asserts that one skilled in the art would readily understand that features used in pacing a selected ventricle could be extrapolated to pacing both ventricles (e.g., simultaneous pacing of both ventricles) given the clear teachings of the specification and in view of the state of the art at the time the invention was made (see, e.g., U.S. Patent 4,928,699 to Mower, U.S. Patents 5,334,222, 5,417,717, and 5,487,752 to Salo, and 5,540,727 to Tockman).

The Examiner poses a number of questions regarding the implementation of various pacing parameters. For example, the Examiner asks "How is the biventricular pacing therapy delivered? How does it [biventricular pacing] account for interventricular conduction delays? Is the pacing delivered to both ventricles at the same time or at different times?" Are one or both ventricles used to initiate the PVARPs? Does the left and right ventricles have different PVARPs? How does the system detect a disruption of ventricular pacing when biventricular pacing is provided? Does the system look to both ventricles or the left or right to detect a disruption?" Does the system change the amount of modification if the left or right ventricle is paced first?" How is the modified pacing timing sequence delivered with the bi-ventricular pacing therapy? Are one or both ventricles used to sense the intrinsic ventricular depolarization? "How is PMT avoided during delivery of the biventricular therapy?"

As set forth in Applicant's statements above, any delay between left and right ventricular paces is negligible in the context of the present invention. As such, Applicant points out that many of the above questions are related to implementation details that are beyond the scope of the invention. To facilitate understanding of the invention, Applicant responds to each of the Examiners questions below.

Q: "How is biventricular pacing therapy delivered?"

Biventricular pacing therapy is delivered as set forth, for example, in Figures 6-22 and as described in the specification. For example, the Vp indicated in Figures 6-22 may correspond to a biventricular pace.

Q: "Is the pacing delivered to both ventricles at the same time or different times?"

This question is beyond the scope of the instant application. None of the claims recite a delay between paced ventricles. Any delay between pacing the ventricles is negligible in the context of the present invention. Whether pacing is delivered to both ventricles at the same time or at different times is not relevant to understanding and implementing the invention.

Q: "Are one or both ventricles using to deliver the V pulse with the pacing timing sequence."

Both independent claims recite pacing therapy delivered to the left and right ventricles.

Q: "Are one or both ventricles used to initiate PVARPS? Does the left and right ventricle have different PVARPS?"

Whether one or both ventricles initiate PVARP or if left and right ventricles have different PVARPs are implementation details that are beyond the scope of the present invention. None of the claims recite or rely on different PVARPs or different initiation of PVARPs for left and right ventricles.

Q: "How does the system detect a disruption of ventricular pacing when biventricular pacing is provided?

The specification describes how disruption of ventricular pacing occurs. For example, at page 10, line 21, the specification describes inhibition of ventricular pacing

when the sinus rate exceeds the pre-programmed AMTR. At page 11, line 3, the specification describes inhibition of ventricular pacing when the patient's heart has intrinsic conduction. Additionally, at page 11, line 7, the specification describes inhibition of ventricular pacing when a PVC occurs. An intrinsic R-wave disrupts ventricular pacing. Various pacing timing sequences discussed in the specification, including those illustrated by Figures 6-22 restore consistent ventricular pacing following a sensed R-wave.

Q: Does the system look to both ventricles of the left or right to detect the disruption?

Whether left or right ventricles are used to detect a disruption of ventricular pacing is an implementation detail that is beyond the scope of the application. Whether the left or right ventricle is used for detection of the disruption of ventricular pacing is not relevant to understanding and implementing the invention.

Q: Does the system change the amount of modification if the left or right ventricle is paced first?

This question is an implementation detail that is beyond the scope of the present application. There is no requirement that the Applicant discuss in the application implementation details that not relevant to understanding the invention as claimed.

Q: How is the modified pacing timing delivered with the biventricular pacing therapy?

As previously described, any of the modified pacing timing sequences discussed in the application, e.g., as illustrated by Figures 6-22 and elsewhere, may be delivered with pacing to both ventricles.

Q: Are one or both ventricles used to sense the intrinsic depolarization?

Whether left or right ventricles are used to sense the intrinsic depolarization is an implementation detail that is beyond the scope of the application. Whether the left or right ventricle is used for sensing is not relevant to understanding and implementing the invention.

Q: How is PMT avoided during delivery of biventricular therapy?

One way PMT avoidance is specifically discussed in the example of Figure 12.

The Examiner refers to U.S. Patent 6,477,415 as showing necessary detail to answer questions such as the ones raised by the Examiner. Applicant points out that the publication date of U.S. Patent 6,477,415 is 2002 and the priority date for Applicant's invention is 1997. Thus U.S. Patent 6,477,415 does not reflect the state of the art at the time of Applicant's invention and may include additional implementation details that are not necessary for the operation of Applicant's invention.

The specification clearly states that the embodiments described are directed to pacing the ventricles. Applicant respectfully asserts that one skilled in the art at the time of Applicant's invention would understand how to pace both ventricles to achieve the illustrated timing sequences with biventricular pacing. No further elaboration is needed regarding PVARPs, initiating timing sequences from right or left ventricles, right or left ventricular sensing and like questions, because everything (PVARPs, sensing, modification of pacing timing sequences, etc.) described in the specification and/or illustrated in the drawings is exactly the same for pacing one ventricle or pacing both ventricles. These and other parameters are described and illustrated in combination with pacing the ventricles. The specification fully enables and supports Applicant's claims.

Claims 1, 2, 5-8, 11-13, 17-19, 21, 24-27, 30-32, 36 and 38-43 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

According to the Examiner, in claims 1, 11-13, 21 and 36, "ventricular pacing" is vague. Without acquiescing to the Examiner's rejections, these claims have been amended rendering the rejections moot.

Claim 17 has been amended to specifically recite the step of detecting an intrinsic depolarization.

Claims 18, 41, and 42 have been cancelled.

Claim 21 has been amended to positively recited that the pulse generator implements a pacing timing sequence. Claim 21 has been amended and no longer recites the term "biventricular pacing therapy."

Applicant respectfully asserts that all claims are now in condition for allowance. Authorization is given to charge Deposit Account No. 50-3581 (GUID.150DIV4) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact her at the number listed below to discuss any issues related to this case.

Respectfully submitted,

HOLLINGSWORTH & FUNK, LLC
8009 34th Avenue South, Suite 125
Minneapolis, MN 55425
952.854.2700

Date: December 26, 2006 By: 

Clara Davis
Reg. No. 50,495